DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1000305562

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Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

04-BLT-25

June 25, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQEUSTED

William F. Nickle
2432 Theodore Road
North East, Maryland 21901-2132

Dear Mr. Nickle,

The Food and Drug Administration conducted an inspection at your operation, located at 2432 Theodore Road, North East, Maryland, on April 7, 2004. The inspection confirmed that you purchased and later sold for slaughter, a bob veal calf that was adulterated within the meaning of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

On March 2, 2004, you sold a bob veal calf, identified with back tag #4507, at [redacted] livestock auction. On March 2, 2004, the bob veal calf, back tag #4507, was sold for slaughter as human food to [redacted] Pennsylvania. The United States Department of Agriculture (USDA) analysis of kidney tissue samples collected from that animal, slaughtered on March 3, 2004, confirmed the presence of 2.32 parts per million (ppm) of neomycin. There is no established tolerance for neomycin in calves (Title 21, Code of Federal Regulations (CFR), Part 556.430). The presence of neomycin at the level reported in this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions that are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the FD&C Act. The insanitary conditions observed at your cattle farm included:

- you fail to maintain drug treatment records for all medicated animals;
- you fail to systemically review treatment records prior to offering an animal for slaughter for human food; and
- failure to have a system for ensuring that drugs or medicated feeds have been used only as directed and that appropriate withdrawal times have been observed.

You are adulterating the medicated milk replacer, which contains neomycin, when you used it in calves to be processed for veal contrary to the warning on their labels. Since the FD&C Act does not permit the extralabel use of medicated feeds, your actions cause the milk replacer to be unsafe to use under section 512(a) of the FD&C Act and adulterated within the meaning of section 501(a)(6) of the FD&C Act.

The violations listed above are not intended to be an all inclusive list. It is your responsibility to assure that your operations are in compliance with the law. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to achieve prompt corrective action may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the investigation and in this letter, and should include copies of any documentation demonstrating that corrections have been made.

Please direct your reply to Ms. Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215.

Sincerely,

Lee Bowers
Director, Baltimore District

Cc: Julie A. Cornett, D.V.M
Branch Chief, Standards and Procedures
USDA/FSIS/Technical Service Center
Landmark Center, Suite 300
1299 Farnam Street
Omaha, Nebraska 68102